# 510(k) Summary

k130762

APR 29 2013

## A. Submitter

Aalto Scientific, Ltd.
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*Contact Person*

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Regulatory Affairs Manager
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*Date of Summary Preparation*

April 19, 2013

## B. Device Identification

| | |
|---|---|
| Product Trade Name: | Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set |
| Common Name: | Audit® MicroCV™ Therapeutic Drug (TDM) Linearity |
| Review Panel: | Chemistry 75 |
| Classification Names: | Assay QC Material |
| Device Classification: | Class I, reserved |
| Product Code: | JJY |
| Regulation Number: | 21 CFR 862.1660 |

## C. Device to Which Substantial Equivalence is Claimed

Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set
Aalto Scientific, Ltd.
Carlsbad, California

510(k) Number: K082714

## D. Device Description:

The Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set is an in-vitro diagnostic device consisting of five levels of Lyophilized linearity material containing Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Lithium, Methotrexate, Phenobarbitol, Pheytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valporic Acid and Vancomycin and additives in human serum. There are five vials labeled A, B, C, D, and E, and contain 5 mL for each level.

Materials of human origin used in the manufacture of this linearity set has been tested using FDA approved methods and found to be non-reactive for HbsAg and antibodies to HCV and HIV-1/2.

| Levels | Catalog Number | Configuration |
|---|---|---|
| A, B, C, D, E | K707M-5 | 5 x 5 mL |

**E. Value Assignment:**

All analytes but Lithium value assignment for Levels A through Level E is performed on one Abbatt Axsym instrument by using Abbott reagents. Lithium value assignment for Levels A through Level E is performed on one Roche Hitachi 911 instrument by using Pointe Scientific reagent. Each analyte was measured 5 times (5 separate vials) and the mean value of each analyte was used to establish target concentration values at each level. The target ranges were calculated as ± 15% of the target value. The mean concentration values of each level were plotted (concentration value vs. assigned level) and a linear regression value was obtained. If the five-point linear regression value is greater than 0.90 and if the plots are linear then the products demonstrate linearity.

**F. Intended Use:**

The Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set is an assayed quality control material consisting of five levels of human based serum. Each level contains: Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Lithium, Methotrexate, Phenobarbitol, Pheytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valporic Acid and Vancomycin. These five levels demonstrate a linear relationship to each other for their respective analytes. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Lithium, Methotrexate, Phenobarbitol, Pheytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valporic Acid and Vancomycin.

The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling and may be used as quality control material for these analytes. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set should not be used for calibration or standardization of the Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Lithium, Methotrexate, Phenobarbitol, Pheytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valporic Acid and Vancomycin assays. The Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set is "For In Vitro Diagnostic Use Only".

**G. Comparison with predicate**

*Similarities and differences between new and predicate devices*

| Characteristics | Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set (Modified) | Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set (Unmodified-K082714) |
|---|---|---|
| *Similarities* | | |
| Intended Use | Linear, calibration verification quality control material | Linear, calibration verification quality control material |
| Number of levels per set | 5 | 5 |
| Contents | 5 x 5 mL | 5 x 5 mL |

| Matrix | Human Based Serum | Human Based Serum |
|---|---|---|
| Type of Analytes | Clinical Chemistry | Clinical Chemistry |
| Form | Lyophilized | Lyophilized |
| Preservatives | Sodium Azide | Sodium Azide |
| Storage | 2 to 8° C<br>for 24 months | 2 to 8° C<br>for 24 months |
| Open Vial Stability | 7 days at 2 to 8° C | 7 days at 2 to 8° C |
| Sterile | No | No |
| *Differences* | | |
| Number of Analytes per vial | 15 | 14 |
| Analytes | Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, **Lithium,** Methotrexate, Phenobarbitol, Pheytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valporic Acid and Vancomycin | Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Methotrexate, Phenobarbitol, Pheytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valporic Acid and Vancomycin |

## H. Statement of Supporting data:

Stability studies have been performed to determine the open vial stability and shelf life for the Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:
Open Vial Stability: 7 days at 2 - 8° C.
Shelf-life Stability: 24 months at 2 - 8° C.

## I. Conclusion:

Based upon the performance characteristics indicated above, Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set is substantially equivalent to the predicate device K082714.

All supporting data is retained on file at Aalto Scientific, Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2013

Aalto Scientific, Ltd.
C/O Dessi Lyakov
1959 Kellogg Ave.
CARLSBAD CA 92008

Re: K130762
Trade/Device Name: Audit™ MicroCV™ Therapeutic Drug (TDM) Linearity Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: I, reserved
Product Code: JJY
Dated: March 19, 2013
Received: March 29, 2013

Dear Dessi Lyakov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K130762

**Device Name:** Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set

**Indications For Use:**

The Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set is an assayed quality control material consisting of five levels of human based serum. Each level contains: Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Lithium, Methotrexate, Phenobarbitol, Pheytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valporic Acid and Vancomycin. These five levels demonstrate a linear relationship to each other for their respective analytes. It is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Lithium, Methotrexate, Phenobarbitol, Pheytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valporic Acid and Vancomycin.

The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling and may be used as quality control material for these analytes. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set should not be used for calibration or standardization of the Acetaminophen, Amikacin, Carbamazepine, Digoxin, Gentamicin, Lithium, Methotrexate, Phenobarbitol, Pheytoin, Quinidine, Salicylate, Theophylline, Tobramycin, Valporic Acid and Vancomycin assays. The Audit® MicroCV™ Therapeutic Drug (TDM) Linearity Set is "For In Vitro Diagnostic Use Only".

Prescription Use __X__ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Yung W. Chan -S

Division Sign – Off
Office of In Vitro Devices and Radiologic Health

510(k): K130762